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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,224	02/13/2001	Hidetaka Osawa	50427-729	7988

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EXAMINER

GORDON, BRIAN R

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 11/13/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

CLD 22 17

Office Action Summary

Application No.

09/781,224

Applicant(s)

OSAWA ET AL.

Examiner

Brian R. Gordon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 14-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 14-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed August 27, 2003 have been fully considered but they are not persuasive. Applicant states on page 15 of the remarks, although Maiefski et al. discloses a general fluid drawing and dispensing apparatus there is no disclosure of the relationship of the first speed and the second speed. As previously recited, the claims are drafted in a manner in which the speed at which the piston moves is in the form of a process limitation. The relationship of the speeds is not a structural limitation of the device. The position changing means is a means for changing positions and is not considered to include the function of changing speeds. The claim as drafted expresses intended use of an element to change the speeds of the piston. On page 16, line 2 applicant states that the technique (method of use) significantly differs from the technique disclosed in Maiefski et al. The examiner asserts that the technique in which a device is used is directed to the intended use of the device not the structure.

Although technical usage, is considered intended use, the examiner asserts that the embodiments of Maiefski et al. disclosed in column 13, line 5 – column 14, line 23 are capable of being operated in the manner intended by applicant.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

It appears as if applicant is attempting to use means plus function language. However, the function is not directly connected to the position changing means. Applicant's arguments are not commensurate in scope with the claims since the

function is not directly connected the position changing means and there is nothing about the rate of moving the piston during aspiration being such tat air is prevented from entering. Thus, claim 1 covers a situation that exceeds the scope argued.

Claim 31 requires a position changing means for changing the position of the piston. It is further recited that the position changing means includes a motor and a piezoelectric element each for changing the position of the piston. The motor and piezoelectric element do not inherent the means plus function limitation of the position changing means. The claim as broadly interpreted only requires a position changing means that includes a motor and a piezoelectric element. The purpose or intended use of the motor and piezoelectric element is not structural limitations.

Kowallis discloses a shifting means (position changing means that changes the position of the system) that incorporates a piezoelectric element. The examiner asserts that by modifying the system of Maiefski et al. to include such a piezoelectric element would have allowed for the entire system to be shifted of moved to a desired location for dispensing or aspiration.

In an effort to expedite the prosecution of the claims, a telephonic interview was held with Edward J. Wise on November 5, 2003, in which the examiner suggest that claims 31-41 be canceled and claims 1, 21, 42, and 43 be amended to recite the following:

Claims 1, 42 and 43....a position changing means including a means for varying sliding speed of said piston, wherein said means for varying said sliding speed is an actuator for....."

Claim 21.... a position changing means including a means for varying a pulse rate of said piston, wherein said means for varying said pulse rate is a linear pulse motor for....."

Applicant refused the proposed amendment as suggest by the examiner.

For reasons given herein, the previous rejection of paper no. 15 is hereby maintained.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-2, 4-5, 14-30, and 43-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Maiefski et al., US 6,416,718.

Maiefski et al. teach a wash station assembly and method for washing selected samples in a sample containing assembly. The wash station assembly includes a wash station having a frame and a fluid dispensing assembly connected to the frame. The fluid dispensing assembly has a selector valve that is connectable to a plurality of fluid lines and is adjustable to allow only one of the fluids to pass through the selector valve

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at a time. An array of syringes (pipettes) is coupled to the selector valve and positioned to receive the fluid passing through the selector valve. Each syringe includes a check valve that prevents backflow of fluid or air into the syringe through the pipetting needles. The wash station assembly 10 includes a wash station 11 that is operatively connected to a programmable controller 26, such as a computer or the like, for automated control.

As best seen in FIG. 8, each syringe 42 includes a bottom connector 130, a barrel 131 fixedly connected to the connector, and a plunger 134 (piston) slidably positioned within the barrel. The connector 130 and barrel 131 define an interior area 136 of the syringe that is adapted to receive a selected amount of the solvent therein. The distribution manifold 40 (pipette holding means) directs the solvent into each syringe 42 through a pair of inlet apertures 140 in the connector 130, which is removably positioned in a respective syringe aperture 100. The connector 130 has a plurality of threads 132 that engage the distribution manifold 40 and retain the syringe 42 in the syringe aperture 100. The connector 130 has an annular groove 138 that communicates with the downstream portion 112 of the manifold's distribution channel 94 for that syringe. The inlet apertures 140 are positioned in the annular groove 138 and connected to the syringe's interior area 136. Accordingly, the solvent flows into the annular groove 138 and enters the syringe's interior area 136 through the inlet apertures 140.

The connector 130 also includes a connection portion 142, such as a Luer connector, that is adapted to removably connect to the pipetting needle 32. The connection portion 142 has an outlet passageway 144 therethrough that is coaxially

aligned with and in communication with the syringe's interior area 136. The outlet passageway 144 allows the solvent in the syringe's interior area 136 to be pushed out of the barrel 131 by the plunger 134, thereby forcing the solvent into and through the pipetting needle 32.

The connector 130 in the exemplary embodiment includes a check valve 146 positioned in the outlet passageway 144 to prevent backflow from the pipetting needle 32 into the syringe 42. The check valve 146 is movable between open and closed positions. In the open position, so solvent can flow out of the syringe's interior area 136 through the outlet passageway 144. In the closed position, the check valve 146 prevents fluid from backflowing through the valve seat 148.

Referring again to FIG. 8, the syringe's plunger 134 is axially movable within the barrel 131 to draw solvent into the syringe's interior area 136 and to dispense the solvent from the syringe. The plunger 134 includes a plunger tip 156 having a plurality of flexible ribs 158 that sealably engage the walls of the barrel 131. In exemplary embodiments, the syringe's barrel 131 is a glass or stainless steel barrel that provides for a very smooth surface for an efficient and effective seal between the barrel and the plunger tip's ribs 158.

The plunger tip 156 is connected to a plunger rod 160 (piston) that projects out of the barrel's open upper end. The plunger rod 160 is connected at its upper end 162 to a respective adjusting screw 166 mounted in an aperture 164 in the upper support plate 44 (piston holding means). The plunger rod's upper end 162 includes a ball swivel 168 that is rotatably captured in a receiving pocket 170 in the adjusting screw 166.

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Accordingly, the plunger rod's axial alignment within the barrel 131 is adjustable so as to prevent the plunger rod 134 from binding within the barrel during the discharge or aspirating strokes. A locking nut 167 is secured to the adjusting screw 166 to lock the adjusting screw and plunger rod 160 in place after the plunger rod is adjusted to its proper axial position.

As best seen in FIG. 8, the plunger 134 is movable axially within, the barrel 131 between a lowered, dispensed position, shown in solid lines, and a raised, aspirated position, shown in phantom lines. As the plunger 134 is moved from the lowered, dispensed position axially toward the raised, aspirated position, solvent is drawn into the syringe's interior area 136 through the inlet aperture 140 in the syringe's connector 130. When the plunger is fully moved to the raised, aspirated position, the syringe 42 is loaded with a predetermined amount of the solvent.

When the syringe 42 is loaded and the plunger 134 is moved through a discharge stroke to the lowered, dispensed position, the plunger tip 156 forces the solvent out of the syringe. The volume of the solvent dispensed is closely controlled by controlling the stroke length during the aspirating as the plunger 134 is moved from the raised, aspirated position.

Dispensing of the solvent is also closely controlled, depending upon the solvent and the washing process being performed. In one embodiment, the plunger's dispensing stroke is a continuous stroke from the raised aspirated position to the lowered dispensed position to provide a continuous flow into the reaction chamber. In an alternate embodiment, the dispensing stroke includes a pulsating stroke, wherein the

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plunger stops periodically at intermediate positions between the raised, aspirated position and the lowered, dispensed position, thereby providing a pulsating dispensement of the solvent into the reaction chamber (position changing means).

As best seen in FIG. 9, the pipetting needle 32 (attachable nozzle cap for jetting liquid) has a conventional Luer lock hub 170 that removably connects to the connection portion 142 of the syringe's connector 130. The pipetting needle 32 includes a hollow shaft 172 with an interior channel 174 that receives the solvent from the syringe's connector 130. The distal end of the needle's shaft 172 includes a plurality of substantially radially directed apertures 176 that communicate with the hollow needle's interior channel 174. The radially directed apertures 176 are sized to allow the solvent passing through the needle 32 to be dispensed radially outwardly relative to the needle.

The drive mechanisms 194 are interconnected by a drive belt 196 that is operatively connected to a drive motor 198 mounted to the upper support plate 44. The drive motor 198 is operatively connected to the controller 26 (not shown) such that the drive motor is selectively started and stopped by the controller. In the exemplary embodiment, the drive motor 198 includes an encoder that communicates with the controller 26 for highly accurate control of the drive motor, thereby providing highly accurate control of the plunger's position within the syringe 42 for accurate aspirating and dispensing of the solvent.

As to the speeds at which the liquid is aspirated and dispensed and the short distance, as presented in claims, these ideas are in the form of method step limitations and do not add any structural limitations to the claims.

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If applicant intends to claim that there is an element in the invention that computes, determines, calculates, or etc. the short distance, this element should be positively claimed.

Claims 1 and 43 are essentially duplicate claims. One of the claims should be canceled.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 3 and 31-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maiefski et al. as applied to claims 1-2, 4-5, 14-30, and 43-44 above, and further in view of Kowallis US 6,245,297.

Maiefski et al. does not disclose a position changing means that comprises a piezoelectric actuator.

Kowallis teaches a method and apparatus for dispensing small volumes of selected substances, such as biological reagents or samples, onto substrates. Any suitable transfer instrument or head can be used, including contact and/or non-contact type devices. For example, the apparatus can employ a transfer head having an elongated tip in the nature of a pin or rod. In a typical construction, a relatively narrow rod is employed, e.g., one having a distal end less than about 500 mm in diameter, and preferably less than about 250 mm in diameter. In another exemplary arrangement the tip includes a channel of capillary size (e.g., less than about 1 mm in diameter) adapted to draw in a liquid reagent, when shifted into contact therewith, by way of capillary action. Still further embodiments contemplate the use of a micropipette, syringe device, jetting apparatus, or other "sip and spit" assembly, as the transfer tip. Shifting means 48 are operatively connected to transfer tip 46 for moving it along axis A, toward and away from its raised position. The shifting means can be, for example, an actuator, such as a z-motion actuator adapted to move the transfer tip in a linear or vertical fashion. In one exemplary arrangement, a solenoid assembly includes a solenoid piston

movable between two positions. The lower end of the piston, in this embodiment, is connected to the upper end of the transfer tip. Upon activation, the piston is drawn downwardly (z direction), thereby shifting the transfer tip to its lowered position. Upon release, the piston returns to its normal, raised position, e.g., under spring bias, thereby shifting the transfer tip to its raised position. Many solenoids are available from commercial sources, and suitable models can be readily chosen by those skilled in the art. In one embodiment, the solenoid is operable to shift the transfer tip up and down over a stroke of from about 2 to about 3 cm, and preferably about 2.5 cm.

Other devices, useful as shifting means, include, for example, pneumatic, hydraulic, magnetostrictive, and piezoelectric actuators, as well as motor assemblies (e.g., steppers).

It would have been obvious to one of ordinary skill in the art to recognize that the plunger/piston actuating means of Maiefski et al. may be modified to incorporate a number of well known actuating devices including piezoelectric as taught by Kowallis, for piezoelectric actuators allow for faster and more accurate dispensing of minute volumes of liquid than that of other conventional actuators.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is (703) 305-0399. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

brg
November 10, 2003



ARLEN SODERQUIST
PRIMARY EXAMINER